

Milwaukee County EMS Research Policy and Data Use Procedure

Enclosed are the Milwaukee County EMS System Research Policy and Data Use procedures.

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Please review and complete the appropriate documents prior to proceeding with any data request or research proposal. If you have any questions, please do not hesitate to contact:

Ronald G. Pirrallo, MD, MHSA
Associate Professor
Medical Director,
Milwaukee County EMS
Chairperson, EMS Research Committee

Milwaukee County EMS Research Policy and Data Use Procedure

Overview and Mission Statement

The Milwaukee County Emergency Medical Services system serves Milwaukee County citizens through Milwaukee County Division of Health Programs in conjunction with Milwaukee County EMS Council, Milwaukee County municipalities and with medical direction from the Medical College of Wisconsin. The system consists of:

- nineteen full-time Paramedic Units, several part-time Paramedic Units and numerous Paramedic First Response and Basic Life Support (BLS) Units that serve the Milwaukee County area;
- an Administrative Section that provides direction of daily operations; administration of contracts, agreements and renewals; direction of EMS services by the Airport Fire Department and other outreach services; State Plan compliance and compliance with State and Federal Regulations and Milwaukee County Ordinances;
- a Communications Center (Base) that provides the communication link between paramedic units, receiving hospitals and medical staff;
- an Education Center that provides paramedic and continuing education and offers other EMS related courses;
- a Quality Assurance Department that monitors prehospital care, controlled substances and a department wide quality management program;
- a Health Information Management Department that maintains a patient database; and
- a Community Outreach Program, including the AHA approved Community Training Center.

The Milwaukee County EMS System recognizes the value of scientific research and sharing of data. The mission of the Milwaukee County EMS System is to provide quality prehospital emergency care to the community through operations, education and information management. Prehospital care will be provided in a timely and effective manner to reduce death, disease, disability, discomfort, dissatisfaction and destitution, which result in the improvement of the health of the individual and our community. All data requests and study proposals must directly support this mission and have, as an end result, the potential of realistically improving prehospital care and patient outcomes.

Milwaukee County EMS has designated the Medical College of Wisconsin (MCW) Institutional Review Board (IRB) for Federal-Wide Assurance of Protection of Human Subjects. When appropriate, all data requests and research proposals must be submitted to the Medical College of Wisconsin IRB and requisite governing and advisory bodies to assure patient safety and compliance with all local, state and federal legal requirements.

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EMS RESEARCH COMMITTEE POLICY

A. Purpose of the EMS Research Committee:

1. To evaluate prehospital care research proposals with direct human subject involvement and their impact on Milwaukee County EMS system operations.
2. To prioritize research activities within the Milwaukee County EMS system.
3. To facilitate researcher development through constructive feedback on research proposals and grant applications.
4. To coordinate EMS data collection.
5. To approve EMS research proposals for submission to the Medical College of Wisconsin Institutional Review Board.

B. EMS Research Committee Members:

1. CHAIRPERSON, Director of Medical Services
2. Milwaukee County EMS Program Director
3. Milwaukee County EMS Education Manager
4. Milwaukee County EMS Quality Manager
5. Milwaukee County EMS Health Information Manager
6. Milwaukee County EMS EMT-P Faculty Member
7. MCW Department of Emergency Medicine, Research Director
8. MCW Pediatric Department of Emergency Medicine, EMS Medical Director, when applicable.
9. Fire Chief representative from an ALS host community.
10. Paramedic representative from an ALS host community.

C. Policy

1. The EMS Research Committee will meet to discuss research proposals that affect Milwaukee County EMS system operations.
2. The researcher must submit their proposal to the Chairperson of the Milwaukee County EMS Research Committee.
3. Only research proposals submitted in the required format will be reviewed.
4. Approval of EMS research proposals will be reached by a consensus of the committee.
5. Research proposal submission to the IRB will not be undertaken until approved by the EMS Research Committee.

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EMS RESEARCH TYPES

EMS Research is categorized into four types with each requiring the completion of a Data Request Form along with specified approvals prior to data use.

1. Quick search
 - a. A quick EMS data search is defined as descriptive in nature, on a limited data set, and requires no further data management actions. This includes data collection in preparation for a research proposal.
 - b. This should require no more than a 30-minute time commitment by Milwaukee County EMS staff.
 - c. Example: What is the number of adult cardiac arrest patients aged 21 years or older who are transported to XYZ hospital?
2. Research Proposal – Direct Human Subject Involvement
 - a. Research proposals include request for data and or data analysis for the purpose of testing a stated hypothesis or answering a specific question.
 - b. Requires a meeting with the EMS Research Committee to discuss the affect on EMS system operations.
 - c. The written decision of the EMS Research Committee will be provided to the principal investigator and is final.
 - d. All EMS data will be compiled by the Milwaukee County EMS Health Information Manager or his/her designee.
3. Research Proposal – Data Collection Only
 - a. Research proposals include request for data and or data analysis for the purpose of testing a stated hypothesis or answering a specific question.
 - b. Does NOT require a meeting with the EMS Research Committee.
 - c. All EMS data will be compiled by the Milwaukee County EMS Health Information Manager or his/her designee.
4. Non-Research Related Data Use
 - a. Non-research related data is defined as statistics or data that are for non-peer reviewed publications or presentations.
 - b. Non-research related data use requests may receive expedited approval from the Milwaukee County EMS Medical Director and the Program Director.
 - c. Non-research related data use requests must comply with the format and content requirements established by the EMS Research Policies.

A per hour fee may be assessed for requested data searches, data retrieval and generated reports. The fee reimburses for staff time and computer use.

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MEDICAL RECORD DEPARTMENT POLICIES

OWNERSHIP AND CONFIDENTIALITY;

The EMS patient care data maintained by the Milwaukee County EMS office are the property of Milwaukee County. These records contain confidential medical information covered under Wisconsin Statutes 146.81-84, 146.50 12(a)(b), and the Federal Privacy and Security Standards, HIPAA.

POLICIES:

1. All research proposals requiring data abstraction must be submitted to the Health Information Manager at Milwaukee County EMS using the Data Request Form.
2. All requests are subject to the EMS Research policies and approval by the Milwaukee County EMS Medical Director and the Milwaukee County EMS Program Director.
3. Priority of time and personnel will be regulated by the normal activities of the department. Requests for data may not interfere with completion of the assigned functions of Milwaukee County EMS.
4. Review of EMS records for quality assurance or for purposes other than approved research, must have Milwaukee County EMS administrative approval in advance by the Medical Director.
5. Every effort should be made to use the computer database. Requests to pull or print original records should be made only to obtain essential information which is not entered in the computer. Original records will only be pulled or printed under the direction of the Health Information Manager.
6. EMS records may be reviewed and printed by using Internet access to the database by authorized personnel. Prior arrangement must be made with the Health Information Manager.
7. All requests for copies of EMS records will be directed to the Health Information Manager for appropriate Release-Of-Information procedures. Research personnel obtaining copies of EMS records are responsible for maintaining confidentiality of all information. A standard fee of fifty cents (\$0.50) per page will be charged for requests over ten pages.
8. Reasonable fees will be charged for Milwaukee County EMS data including, but not limited to, personnel, computer, and processing time.

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Milwaukee County EMS System DATA REQUEST FORM

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NAME OF REQUESTER _____

AFFILIATION/INSTITUTION _____

ADDRESS _____

CONTACT TELEPHONE # _____

CONTACT EMAIL _____

Identify Research Type: _____ A. Direct Human Subject Involvement, _____ B. Data Collection Only,
_____ C. Quick Search (in preparation for proposal), or _____ D. Non-Research Related Data Use

1. DATE DATA REQUESTED _____ 2. DATE DATA NEEDED _____

3. DATA TO BE COLLECTED (Identify specific parameters of data to be reported, including time span of requested data search) _____

4. QUESTION TO BE ANSWERED BY DATA _____

5. IS DATA REQUEST A COMPONENT OF: _____ RESEARCH STUDY _____ GRANT OR
_____ OTHER (Identify how data will be used) _____

6. TITLE OF STUDY, PROPOSAL OR GRANT _____

7. IRB OR HRRC APPROVAL? _____ YES, Date of Approval _____

_____ NO, Explain _____

a. I hereby agree that prehospital data collected for this study/proposal is to be used solely for the above stated investigation.

b. This agreement is non-transferable; no information shall be released to persons not connected with the study.

c. No patient will be identified in any publications resulting from this study

d. Following study completion, all patient identifiable information will be disposed of in a confidential manner, by either shredding or burning.

e. The Requester agrees to provide a copy of any and all publications resulting from the use of these requested data.

f. The Requester agrees to acknowledge the Milwaukee County EMS system as the source of the data in all presentations, disclosures and publications.

g. A per hour fee may be assessed for requested data searches, data retrieval and generated reports. The fee reimburses for staff time and computer use.

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Milwaukee County EMS System

DATA REQUEST FORM

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Signature of Principal Investigator

Date

SUBMIT COMPLETED FORM TO:

Lauryl M. Pukansky, RHIA

Health Information Manager

Milwaukee County EMS

1220 W. Vliet St, Suite 304

Milwaukee, WI 53205

Phone: (414) 289-5821

Fax: (414) 289-8528

Email: lpukansky@milwcnty.com

-----Department Use Only-----

REQUEST APPROVED _____ DENIED _____

EXPLANATION _____

APPROVED BY:

Ronald G. Pirrallo, MD, MHSA
Medical Director, Milwaukee County EMS
Signature _____

____ YES ____ NO DATE _____

Program Director, Milwaukee County EMS
Signature _____

____ YES ____ NO DATE _____

Estimated Preparation Time _____

Estimated Fee _____

Date Requester Notified _____

Fee Acceptance ____ YES ____ NO

INVOICE SENT TO:

Name _____

Address _____

City _____ Zip code _____

DATE DATA SENT _____ ASSESSED FEE _____

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Updated: 01/08/07

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Patient Care Record Correction Form

In an effort to ensure accurate and complete EMS System information, we request that you notify us of any inconsistencies or errors detected during the course of your investigation or study.

Please complete and return this form to the Milwaukee County EMS office as soon as possible.

TITLE OF STUDY _____

MED UNIT NUMBER _____ RUN REPORT DATE _____

REPORT CASE NUMBER _____PATIENT NAME _____

NATURE OF ERROR OR INCONSISTENCY TO BE REVIEWED FOR CORRECTION:

[illegible]

SUBMITTED BY: _____

DATE: _____

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EMS Research-Related Policies

1. All research proposals affecting the Milwaukee County EMS System must be submitted for review to the EMS Research Committee.
2. Final approval for all research proposals must be granted by the Medical Director and Program Director of the Milwaukee County EMS System.
3. The Medical Director or Program Director reserves the right to delay the implementation of any study to best coordinate EMS System operations.
4. Overlapping study protocols that require a significant change in standard operating procedures or patient care protocols are discouraged. The EMS Research Committee will determine the feasibility of implementation of more than one ongoing study.
5. All study protocols should be ideally implemented system-wide and not limited to one section of the community or to a single EMS provider agency.
6. In-service of EMS personnel on research protocols must be coordinated with regularly scheduled continuing education sessions, refresher classes and distance learning requirements.
7. The budget for funded studies should be developed in conjunction with the Milwaukee County EMS Program Director to cover reasonable expenses. Funded studies will be given priority consideration for implementation. The cost and compensation of education of system providers and staff will be predetermined and agreed upon by MCEMS and the researcher.
8. The Milwaukee County EMS Office will coordinate all correspondence with the study investigator. Direct calls should not be made by the investigator to EMS field personnel or EMS agency administration.
9. Study investigators will provide regular progress reports to the Milwaukee County EMS System.
10. All research proposals will comply with the format and content requirements established by the EMS Research Committee.
11. All research proposals shall be presented for review, comment and endorsement by the Milwaukee County Council on Emergency Medical Services.
12. All research proposals will identify a member of the Milwaukee County EMS Office and/or the MCW Department of Emergency Medicine as a co-investigator to liaison with the EMS System and facilitate protocol compliance and study integrity.
13. Authorship of publications must follow the requirements set forth by the publication of record. Co-investigators from the Milwaukee County EMS and/or the MCW Department of Emergency Medicine are not considered authors unless they meet publication requirements. All publications related to the research proposal should acknowledge the Milwaukee County EMS System regardless of authorship.

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RESEARCH DATA REQUEST INSTRUCTIONS

(TO BE COMPLETED FOR ALL RESEARCH PROPOSALS IN ADDITION TO THE RESEARCH DATA REQUEST FORM)

Research proposal submissions must contain a Study Summary with sections listed below in the following order:

- 1) Title
- 2) Author / Study Group Information
- 3) Proposal
 - a. Objective
 - b. Methods
 - c. Discussion
 - d. References
- 4) Consent

Beginning with the title page, number the pages consecutively. Use font size 12 or equivalent, double spaced, single sided format. Maximum number of pages excluding references and MCW IRB Application Form is 10. See further details described below.

Title - The title should be short, specific and clear. Do not use abbreviations in the title.

Author / Study Group Information - List the full names, degrees, and institution affiliations of all authors. When more than 6 authors are named, the use of a collective study group name is encouraged.

Proposal - The structured proposal should consist of four sections labeled Objective, Methods, Discussion, and References.

Objective: This section should include a precise statement of the study purpose or hypothesis. Any information, such as past work or controversy, that places the study in perspective should be included here.

Methods: This section should contain the following elements when relevant to the investigation: study design, population, setting, interventions, observations or key outcome measures, analytical methods, and other relevant methodology.

Discussion: This section should describe how the study objective will advance an understanding of the issue under investigation. Include brief justification or interpretive statements on how this study will improve prehospital care.

References: List references in consecutive numerical order. Once a reference is cited, all subsequent citations should be to the original number.

Consent - Studies including human subject investigations must state the format of the informed consent and the risks involved to the study subjects.

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Medical College of Wisconsin Institutional Review Board for Federal-Wide Assurance of Protection of Human Subjects

The Medical College of Wisconsin requires that research investigators must at all times protect the rights, privacy and welfare of individuals participating in research. Under the direction of the Human Research Protection Office (**HRPO**), the Froedtert Hospital (**FH IRB**) and the Medical College of Wisconsin (**MCW HRRC & Fast Track**) Institutional Review Boards hold the primary responsibility to protect human subjects involved in research studies conducted by departments, centers and institutes. The IRB holds the authority to review, approve, modify or disapprove research protocols submitted under its jurisdiction. The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects in an atmosphere of mutual trust and scientific integrity in the pursuit of knowledge.

Further information and investigator submission instructions can be found at <http://infoscope.mcw.edu/research/irc/homepage.htm> or contact:

Human Research Protection Office
Medical College of Wisconsin
8701 Watertown Plank Road, R3100
P.O. Box 26509
Milwaukee, WI 53226-0509

IRB Administrative Assistants

Mary Vigdor mvigdor@mcw.edu

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Phone:(414) 456-8413

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Data Request Check List

1. Was Data Request Form completed for all Quick Search, Research Proposal and Non-Research Related request and signed by the investigator?
2. Was data request sent to the correct person?

SUBMIT COMPLETED FORM TO:

Lauryl M. Pukansky, RHIA

Health Information Manager

Milwaukee County EMS Phone: (414) 289-5821

1220 W. Vliet St, Suite 304 Fax: (414) 289-8528

Milwaukee, WI 53205

Email: lpukansky@milwcnty.com

3. Was a properly formatted and less than 10 page Study Summary submitted, in addition to the Data Request Form, for all research-related requests?
4. Was approval received by the EMS Research Committee prior to the release of any data or submission to the Medical College of Wisconsin IRB?